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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,763	10/23/2001	Robert Bloder	HJW-100US	7526

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EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,763	BLODER ET AL.	
	Examiner	Art Unit	
	Robert D. Rines	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the patent application filed 4 April 2006. It is noted that this application benefits from Provisional Patent Application Serial No. 60/242,996 filed 25 October 2000. Claims 1, 14-15 have been amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[2] Previous rejections under 35 U.S.C. 112, second paragraph are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[3] Claims 1-11 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portwood et al. (United States Patent #6,305,377) in view of Akers et al. (United States Patent #6,112,182), and further in view of Yarin et al. (6,294,999).

[A] As per claim 1, Portwood et al., teaches a method for distributing pharmaceutical products comprising the steps of: developing a disease management program and related materials having specific relevance to a counterpart pharmaceutical product to be distributed in conjunction with said counterpart pharmaceutical product (Portwood et al.; Abstract, col. 2, lines 1-30, and col. 7, lines 16-31); communicating to a doctor said disease management program and said related materials and said relevance of said program and said materials to said counterpart pharmaceutical product (Portwood et al.; col. 7, lines 16-35, and col. 8, lines 14-29); and providing means of communication between said doctor, a patient for whom said doctor has

prescribed said disease management program and its counterpart drug, and said pharmaceutical product supplier (Portwood et al.; col. 6, lines 66-67 and col. 7, lines 1-15).

[i] Although Portwood et al., teaches utilizing data provided by a pharmaceutical product supplier to supply said disease management program related materials (Portwood et al.; col. 7, lines 1-5 and col. 8, lines 15-29), and Portwood et al., teaches the disease management regimen is transmitted to the patient from a central server (Portwood et al.; col. 7, lines 39-45), Portwood et al., fails to teach communication or delivery of the disease management program materials directly to a patient, by a pharmaceutical product provider, in conjunction with said counterpart pharmaceutical product when said patient fills a prescription. Portwood et al. fails to specifically teach the distribution of physical analytical materials to the patient for use in conjunction with the counterpart pharmaceutical product. Portwood et al. further fails to specifically teach the related physical analytical materials to be used by a patient during the disease management program and results obtained from the physical analytical material to be communicated to a doctor.

[ii] Akers et al., does teach a pharmaceutical product supplier providing said disease management program related materials directly to the patient in conjunction with said counterpart pharmaceutical product when said patient fills a prescription (Akers et al.; col. 1, lines 53-67, col. 3, lines 60-67, col. 4, lines 24-32, and col. 7, lines 15-25). Akers et al. further teaches a pharmaceutical supplier initiating and scheduling physical analytical materials to be used on the patient, by a technician at scheduled appointments for the purpose of collecting physiological data that is relevant to the treatment protocol (Akers et al.; col. 7, lines 60-67 and col. 8, lines 1-12). However, Akers et al. fails to teach the related physical analytical materials are distributed to the patient and are to be used by a patient during the disease management program and results obtained from the physical analytical material to be communicated to a doctor.

[iii] However, as is evidenced by Yarin et al., the distribution of physical analytical materials related to a drug treatment protocol to be are to be used by a patient during the disease management program and results obtained from the physical analytical material to be communicated to a doctor are well known in the remote treatment/patient monitoring art (Yarin et al.; col. 9, lines 44-65).

[iv] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Portwood et al., and Akers et al., with those of Yarin et al. Such combination would have resulted in a system and method for prescribing a drug

and an accompanying drug taking/disease management program that would allow a physician to utilize information provided by a pharmaceutical company to determine the best medical regimen, including optimal drug dosages and duration of treatment for the patient (Portwood et al.; col. 2, lines 26-30, col. 7, lines 31, and col. 8, lines 15-29). Further, such system would have allowed for the delivery of disease management information to the patient upon a prescription dispensing transaction (Akers et al.; col. 1, lines 60-67). Additionally, such a system would have expanded on the physiological monitoring features of Akers et al. (Akers et al.; col. 7, lines 60-67 and col. 8, lines 1-12) to include patient collection and reporting of data to a physician of physiological data such as blood pressure, blood glucose levels, or blood coagulation measurements (Yarin et al.; col. 9, lines 43-61). The motivation to combine the teachings would have been to initiate a process for managing a care service process for scheduling appointments for monitoring lifestyle, health or disease states or conditions, printing information on the dispensed drug, and initiating a process to improve the health of the patient (Akers et al.; col. 1, lines 65-67, and col. 2, lines 1-5). Further motivation would have been to employ well-known techniques and products for monitoring a patient's compliance with medication regimens (Yarin et al.; col. 3, lines 20-25) thereby facilitating effective self-management of medication treatment by patients (Yarin et al.; Abstract) and providing opportunity to modify medication regimens for particular medicaments in response to data received from monitoring devices (Yarin et al.; Abstract).

[B] As per claim 2, Portwood et al., teaches wherein said step of developing said disease management program includes developing a plurality of different management programs for each counterpart drug (Portwood et al.; col. 8, lines 14-29, and col. 10, lines 48-67) whereby said doctor can select which of said plurality of management programs should be prescribed along with said drug (Portwood et al.; col. 10, lines 60-67).

[C] As per claim 3, Akers et al., teaches wherein said disease management program includes a diagnostic test for an acute or chronic disease (Akers et al.; col. 7, lines 13-29).

[D] As per claim 4, Portwood et al., teaches further comprising the step of preventing a patient's participation in said disease management program until said patient has received said disease management program materials and said counterpart pharmaceutical product (Portwood et al.; col. 7, lines 35-56).

[E] As per claim 5, Portwood et al., teaches the step of providing an electronic host with a computer readable site on a global computer network for said patient to communicate with said host (Portwood et al., col. 3, lines 42-61, col. 6, lines 1-4 and lines 55-64, and col. 9, lines 35-47).

[F] As per claim 6, Portwood et al., teaches the step of compiling data from said patient (Portwood et al.; col. 7, lines 46-52, and col. 8, lines 37-53).

[G] As per claim 7, Portwood et al., teaches said compiling step is performed via communication with said patient via a global computer network (Portwood et al.; col. 6, lines 1-5, and col. 7, lines 46-56).

[H] As per claim 8, Portwood et al., teaches wherein said means of communication comprises a computer accessible site on a global computer network (Portwood et al.; col. 6, lines 55-64, and col. 9, lines 35-46).

[I] As per claim 9, Portwood et al., teaches wherein said means of communication includes the use of a global computer network (Portwood et al.; col. 6, lines 57-63).

[J] As per claim 10, Portwood et al., teaches the step of providing prescription adherence reminders after said patient fills said prescription (Portwood et al.; col. 6, lines 57-63).

[K] As per claim 11, Portwood et al., teaches the step of waiting until said patient fills said prescription and begins following said disease management program and then contacting said patient for feedback (Portwood et al.; col. 9, lines 59-65).

[i] Regarding claims 2-11, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claims 2-11 and are herein incorporated by reference.

[L] As per claim 14, Portwood et al., teaches a method for distributing pharmaceutical products comprising the steps of: developing a disease management program and related materials to be distributed in conjunction with a counterpart pharmaceutical product (Portwood et al.; Abstract, col. 2, lines 1-30, and col. 7, lines 16-31); communicating to a doctor said disease state management program and said program's relationship with its counterpart drug (Portwood et al.; col. 7, lines 16-35, and col. 8, lines 14-29); not allowing participation of said patient in said disease management program until after said patient has filled said prescription for said disease management program and its counterpart drug (Portwood et al.; col. 7, lines 35-56); and providing a method of communication between said doctor and a patient for whom said doctor has prescribed said disease management program and its counterpart drug (Portwood et al.; col. 6, lines 66-67, and col. 7, lines 1-15).

[i] Although Portwood et al., discloses utilizing pharmaceutical product information provided by a pharmaceutical company to determine a disease management program, Portwood et al., does not specifically teach or require a pharmaceutical supplier to supply said disease management program related materials in conjunction with said counterpart pharmaceutical product. Further, Portwood et al. fails to specifically teach the distribution of physical analytical materials to the patient for use in conjunction with the counterpart pharmaceutical product.

[ii] However, Akers et al., does teach a pharmaceutical product supplier providing said disease management program related materials in conjunction with said counterpart pharmaceutical product (Akers et al.; col. 1, lines 53-67, col. 3, lines 60-67, col. 4, lines 24-32, and col. 7, lines 15-25).

[iii] Akers et al. fails to teach distribution of physical analytical materials to the patient.

[iv] However, as is evidenced by Yarin et al., the distribution of physical analytical materials related to a drug treatment protocol to be are to be used by a patient during the disease management are well known in the remote treatment/patient monitoring art (Yarin et al.; col. 9, lines 44-65).

[v] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Portwood et al., and Akers et al., with those of Yarin et al. Such combination would have resulted in a system and method for prescribing a drug and an accompanying drug taking/disease management program that would allow a physician to utilize information provided by a pharmaceutical company to determine the best medical regimen, including optimal drug dosages and duration of treatment for the patient (Portwood et al.; col. 2, lines 26-30, col. 7, lines 31, and col. 8, lines 15-29). Further, such system would have allowed for the delivery of disease management information to the patient upon a prescription dispensing transaction (Akers et al.; col. 1, lines 60-67). Additionally, such a system would have expanded on the physiological monitoring features of Akers et al. (Akers et al.; col. 7, lines 60-

67 and col. 8, lines 1-12) to include patient collection and reporting of data to a physician of physiological data such as blood pressure, blood glucose levels, or blood coagulation measurements (Yarin et al.; col. 9, lines 43-61). The motivation to combine the teachings would have been to initiate a process for managing a care service process for scheduling appointments for monitoring lifestyle, health or disease states or conditions, printing information on the dispensed drug, and initiating a process to improve the health of the patient (Akers et al.; col. 1, lines 65-67, and col. 2, lines 1-5). Further motivation would have been to employ well-known techniques and products for monitoring a patient's compliance with medication regimens (Yarin et al.; col. 3, lines 20-25) thereby facilitating effective self-management of medication treatment by patients (Yarin et al.; Abstract) and providing opportunity to modify medication regimens for particular medicaments in response to data received from monitoring devices (Yarin et al.; Abstract).

[M] As per claim 15 (Currently Amended), Portwood et al., teaches a method of treating a person with a medical condition using a pharmaceutical product comprising the steps of: developing a disease management program and related materials to be distributed in conjunction with a pharmaceutical product (Portwood et al.; Abstract, col. 2, lines 1-30, and col. 7, lines 16-31); prescribing said pharmaceutical product and said disease management program related materials to a patient (Portwood et al.; col. 7, lines 35-60); communicating with said patient after said patient begins treatment with said pharmaceutical product and said disease management program (Portwood et al.; col. 7, lines 51-60) via a global computer network (Portwood et al.;

col. 6, lines 55-64); and compiling data from said communications with said patient (Portwood et al.; col. 7, lines 51-52).

[i] Although Portwood et al., discloses utilizing pharmaceutical product information provided by a pharmaceutical company to determine a disease management program, Portwood et al., does not specifically teach or require a pharmaceutical supplier to supply said disease management program in conjunction with said counterpart pharmaceutical product when said patient fills a prescription. Further, Portwood et al. fails to specifically teach the distribution of physical analytical materials to the patient for use in conjunction with the counterpart pharmaceutical product.

[ii] However, Akers et al., does teach providing a pharmaceutical supplier to supply said disease management program in conjunction with said counterpart pharmaceutical product when said patient fills a prescription (Akers et al.; col. 1, lines 53-67, col. 3, lines 60-67, col. 4, lines 24-32, and col. 7, lines 15-25).

[iii] Akers et al. fails to teach distribution of physical analytical materials to the patient.

[iv] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Portwood et al., and Akers et al., with those of Yarin et al. Such combination would have resulted in a system and method for prescribing a drug and an accompanying drug taking/disease management program that would allow a physician to

utilize information provided by a pharmaceutical company to determine the best medical regimen, including optimal drug dosages and duration of treatment for the patient (Portwood et al.; col. 2, lines 26-30, col. 7, lines 31, and col. 8, lines 15-29). Further, such system would have allowed for the delivery of disease management information to the patient upon a prescription dispensing transaction (Akers et al.; col. 1, lines 60-67). Additionally, such a system would have expanded on the physiological monitoring features of Akers et al. (Akers et al.; col. 7, lines 60-67 and col. 8, lines 1-12) to include patient collection and reporting of data to a physician of physiological data such as blood pressure, blood glucose levels, or blood coagulation measurements (Yarin et al.; col. 9, lines 43-61). The motivation to combine the teachings would have been to initiate a process for managing a care service process for scheduling appointments for monitoring lifestyle, health or disease states or conditions, printing information on the dispensed drug, and initiating a process to improve the health of the patient (Akers et al.; col. 1, lines 65-67, and col. 2, lines 1-5). Further motivation would have been to employ well-known techniques and products for monitoring a patient's compliance with medication regimens (Yarin et al.; col. 3, lines 20-25) thereby facilitating effective self-management of medication treatment by patients (Yarin et al.; Abstract) and providing opportunity to modify medication regimens for particular medicaments in response to data received from monitoring devices (Yarin et al.; Abstract).

[N] As per claim 16, Portwood et al., teaches wherein said patient chooses to participate in said disease management program in addition to receiving said pharmaceutical product before said prescription is written (Portwood et al.; col. 7, lines 15-41 and Fig. 2).

[i] Regarding claim 16, the obviousness and motivation to combine as discussed with regard to claim 15 above are applicable to claim 16 and are herein incorporated by reference.

[4] Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portwood et al., Akers et al., and Yarin et al. as applied to claim 1 above, and further in view of Baruch et al. (United States Patent Application Publication #2002/0077849).

[A] As per claim 12, although Portwood et al., teaches collecting and reporting patient feedback (Portwood et al.; col. 9, lines 59-65), Portwood et al., fails to teach sharing data with a pharmaceutical product manufacturer.

[i] However, Baruch et al., teaches the step of sharing said feedback with a pharmaceutical product manufacturer (Baruch et al.; paragraph [0064]).

[ii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Portwood et al., and Akers et al., as applied to claim 1 above, with those of Baruch et al. Such a combination would have provider a system capable of querying the patient on health matters to receive an updated status as to the health of the patient, the effectiveness of the prescribed regimen, or any health problems that may have arisen as a result of the prescribed medical regimen (Portwood et al.; col. 9, lines 61-65). The

motivation to combine the teachings would have been to provide a centralized system enabling access to a repository of patient feedback data such that the information collected on each patient could be advantageously utilized for direct marketing of pharmaceuticals to the physicians and/or patients based on their needs (Baruch et al.; paragraph [0015]).

[B] As per claim 13, although Portwood et al., teaches collecting and reporting patient feedback (Portwood et al.; col. 9, lines 59-65), Portwood et al., fails to teach using feedback information to market pharmaceutical products.

[i] However, Baruch et al., teaches comprising the step of using said feedback to market pharmaceutical products (Baruch et al.; Abstract and paragraphs [0015] [0056] [0064]).

[ii] Regarding claim 13, the obviousness and motivation to combine as discussed with regard to claim 12 above are applicable to claim 13 and are herein incorporated by reference.

Response to Arguments

Applicant's arguments filed 4 April 2006 have been fully considered by the Examiner and are considered moot in view of newly added grounds of rejection.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 4 April 2006 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Portwood et al, Akers et al., newly added reference Yarin et al., and Baruch et al, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (mailed 30 December 205), and incorporated herein.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.D.R.

6/12/06

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER